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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	PDT 103 CON(3)	6406

45200 7590 01/28/2008
KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,243	Applicant(s) STEINER ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,19,20,22-27,31,32 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,19,20,22-27,31,32 and 36-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 16, 19, 20, 22-27, 31, 32 and 36-53 are pending in this application.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Action Summary

The examiner acknowledges the cancellation of claims 18, 21 and 54. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

The rejection of claims 16, 22, 52 and 53 under 35 U.S.C. 103(a) as being unpatentable over Sankaram et al. (US 6,132,766) is hereby withdrawn as applicant has amended the claims to remove lipids as the material, which overcomes the rejection over Sankaram et al.

Response to Arguments

Applicant's arguments with respect to claims 16, 19, 20, 22-27, 31, 32 and 36-53 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 31, 32, 36, 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the abovementioned claims the applicant recites in line 11, the phrase "copolymers". It is unclear to the examiner what these copolymers comprise.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16, 19, 20, 22, 27, 32, 37, 38, 39 and 50-53 rejected under 35 U.S.C.

103(a) as being unpatentable over Debenedetti et al. (US 6,063,910) or Sugaya et al. (JP 363020301A) in view of Hunt et al. (US 4,866,051).

Applicant claims a microparticle having a size between 0.5 to 10 microns formed from a material releasing drug at a pH of 6.0 greater and wherein the material comprises alginate, chitosan and hydrophilic or hydrophobic proteins.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Debenedetti et al. teach in column 2, lines 24-15, 31-35 and 61-66, a method of forming protein microparticles, particularly hydrophobic protein microparticles (i.e. insulin, catalase, etc.) having a particle size of less than 10 microns. It is the position of the examiner that the recitation of protein includes all proteins, although it may be preferred that the protein is hydrophobic. Column 3, lines 17-40 teach that the particle can be made of a blend of materials in addition to the protein. These materials include the polymers cited in lines 36-40.

Sugaya et al. disclose highly pure microparticles of chitosan having an average particle diameter of less than 10 microns (abstract) to be used as a carrier in the medical field.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Debenedetti et al. or Sugaya et al. do not disclose the microparticle releasing a drug at a pH of 6.0 or greater or that the particles are stored in a cartridge for insertion into a inhaler. It is for this that Hunt et al. is joined.

Column 3, lines 23-27 of Hunt et al. teach the use of inhalation cartridges comprising particles having a size below 10 microns.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

The claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant (i.e. proteins, amino acids, etc.) would have that limitation as well.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teachings of Boyes et al. comprising dry particles in the invention of Hunt et al. comprising inhalation cartridges for particles. The expected result would be facilitating delivering the microparticle via inhalation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-26 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheatham et al. (US 2005/0153874).

Applicant claims administering microparticles which comprise diketopiperazine and an active agent having a diameter between 0.5 and 10 microns in a pharmaceutically acceptable carrier.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Cheatham et al. disclose a diketopiperazine microparticle that may be administered alone or incorporating and active agent, such as insulin ¶ [0006]. ¶ [0016] teaches that the particle formulation can be encapsulated by polymeric materials such as poly(lactic acid-co-glycolic acid). ¶ [0020] also teaches the claimed invention. ¶ [0006] also teaches that administration of particles can be through a unit dose inhaler.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Cheatham et al. do not teach the size of the particles or that the agent is released at a pH of 6.0 or greater.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that the determination of particle size would have been would have been obvious to one of skill in the art. Since the particles are to be delivered via the pulmonary system and facilitated by a unit dose inhaler, smaller particles are better for providing greater surface area of the drug and less agglomeration of the particles. With respect to the pH of 6.0 or greater, the claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant would have that limitation as well.

Conclusion

Claims 16, 19, 20, 22-27, 31, 32 and 36-53 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-

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Art Unit: 1616

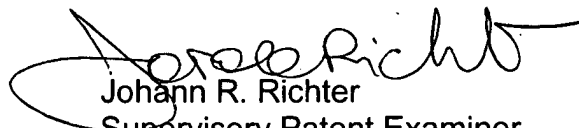
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272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616


Johann R. Richter
Supervisory Patent Examiner
Art Unit 1616